Sustac
(Glyceryl trinitrate)

Tablet
2.6 mg, 6.4 mg

COMPOSITION –

Each tablet contains:

Glyceryl trinitrate 2.6mg

(Product Complies to Manufacturer's Specifications)

Each tablet contains:

Glyceryl trinitrate 6.4mg

(Product Complies to Manufacturer's Specifications)

THERAPEUTIC INDICATIONS

The prophylaxis of angina pectoris

DOSAGE AND ADMINISTRATION

Adults and Elderly Patients:
Dosage should be tailored to the requirements of the individual patient but will usually be 1 or 2 tablets taken three times daily.
Children:
Not recommended.
For oral administration. Sustac tablets must be swallowed whole and not chewed. They are not for sublingual administration. Tablets should be taken between meals.

CONTRAINDICATIONS

As for glyceryl trinitrate. Sustac should not be used in patients with marked anemia, head trauma, cerebral haemorrhage or incipient glaucoma.
Sildenafil has been shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitrates or nitric oxide donors is therefore contraindicated.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

As with other drugs for the treatment of angina pectoris, abrupt discontinuation of therapy may lead to exacerbation of symptoms. When discontinuing long term treatment, the dosage should be reduced gradually over several days, and the patient carefully monitored.

DRUG INTERACTIONS

May enhance the effects of peripheral vasodilators. The hypotensive effects of nitrates are potentiated by concurrent administration of sildenafil.

PREGNANCY AND LACTATION

There is no evidence relating to the safety of nitrates in pregnancy and lactation.
Nitrates should not be administered to pregnant women and nursing mothers unless considered essential by the physician.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None stated.

ADVERSE DRUG REACTIONS

Side-effects include facial flushing and headache. Toxic effects of glyceryl trinitrate include vomiting, restlessness, cyanosis, methemoglobinemia and syncope.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at pv@searlecompany.com

OVERDOSE

In the event of accidental or deliberate overdosage toxic effects of glyceryl trinitrate include vomiting, restlessness, cyanosis, methemoglobinemia, tachycardia and syncope. Patients should receive gastric aspiration and lavage and be given respiratory and circulatory support.
The physician should be aware that tablets in the intestine will release their content over several hours.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Glyceryl trinitrate is a potent coronary vasodilator. It also reduces venous return and thus left ventricular work.

Pharmacokinetic properties

Following oral administration glyceryl trinitrate is rapidly metabolized to glyceryl 1,2 dinitrate and glyceryl 1,3 dinitrate. Although less potent the metabolites probably provide the predominant pharmacological effect. Studies with Sustac 2.6mg and 6.4mg demonstrate a tmax for both metabolites of approximately 1 hour and an apparent t/ of approximately 2 hours. There is evidence of activity extending over 6 hours or more.

PRECLINICAL SAFETY DATA

There are no preclinical data of relevance to the prescriber which are additional to safety data already included in other sections of the SPC

PRESENTATION

Sustac 2.6 mg: 30 sustained released Tablets

Sustac 6.4 mg: 30 sustained released Tablets

STORAGE INSTRUCTIONS

- To be sold on the prescription of a registered medical practitioner only.

- Protect from sunlight, moisture and heat.

- Do not store above 30°C.

- Keep all medicines out of sight & reach of children.

- Product contains Lactose.

REGISTRATION NUMBER

Sustac 2.6 mg

M.L: 000016

R.N: 002992

Sustac 6.4 mg:

M.L: 000016

R.N: 001436

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION – As per registrations letter

Mg. Searle Spac

SEARLE

Manufactured by:

The Searle Company Limited,

F-319, S.I.T.E., Karachi-Pakistan.

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Jun 2021

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